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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/607,766	06/27/2003	David Wynn	MCP-5014 NP	7412

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EXAMINER	
ROGERS, JAMES WILLIAM	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
04/09/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/607,766	WYNN ET AL.	
	Examiner	Art Unit	
	JAMES W. ROGERS	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8-20,22 and 23* is/are pending in the application.

4a) Of the above claim(s) *6,13 and 14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,8-12,15-20 and 22-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/18/2008 has been entered.

Applicants amendments to the claims filed 06/11/2008 have been entered.

Response to Arguments

Applicant's arguments with respect to claims 1-5,8-12,15-20 and 22-23 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,3-4,8-12,15-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Percel et al. (US 6,451,345 B1).

Percel teaches taste masked microcapsules of Linezolid, which can be tabulated into a fast disintegrating tablet or chewable tablet forms. See abstract. The microcapsules were formulated into various dosage forms by combining and mixing with

other excipients including binders such as hydroxypropylcellulose (HPC) and hydroxypropyl methylcellulose (HPMC). Regarding the limitations that moisture content is less than 5%, throughout the examples and disclosure of Percel water was not mentioned in the process to make the dosage form, instead organic solvents were used to make the granules and to coat them, the granules themselves were dry blended with the other components of the tablet and compressed. See examples and col 3 lin 59-64. Thus the moisture content would essentially be zero since no water was added during the manufacturing process. The type of HPMC used in a tablet formulation in the examples of Percel was HPMC K4M, defined by applicants within their specification as a suitable HPMC for use in their own dosage form. See example 7. HPMC has a MW of 82,000 Da, the examiner relies upon the evidence of Dow Chemical Co. Poster presented at the annual meeting and exposition of the American Association of Pharmaceutical Scientists. Since the HPMC used in Percel is the same as in applicants invention it is inherent that it will have the same viscosity in solution since the same compound will inherently have the same properties. The amounts of HPMC used in example 7 was 9 wt% and the amount of coated particles was 69.4 wt% of the total dosage form, both values are within applicants claimed ranges. Percel teaches several different types of polymer can be used as the oatings for the microcapsules including cellulose acetate phthalate (CAP), ethylcellulose (EC), and hydroxypropyl methylcellulose phthalate (HPMCP) in addition to plasticizing polymers and seal coats comprised of shellac. See col 2 lin 59-col 3 lin 58. The amount of coating was preferably 35-45 wt% of the total coated particle, within the examples the weight gain for the

particles after applying the coating was 30%. See examples 1-2. Regarding claim 4, Parcel specifically mentions the use of mannitol for use as a disintegrant in the dosage form. See col 4 lin 21-22. Regarding applicants limitation within claim 16 that a first polymer and second polymer are within a certain weight ratio, the plasticizer (includes PEG a water soluble polymer) was added to the polymer in amounts of 5-30 wt% based on the weight of the polymer, thus the ratio of the 2nd polymer (PEG) to the 1st polymer (CAB) would be 5:95 to 30:70 or 6:14. within applicants claimed range.

Claim Rejections - 35 USC § 103

Claims 1,3-5,8-12,15-20 and 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over McTeigue et al (US 2002/0031552 A1, cited previously) in view of Percel et al. (US 6,451,345 B1).

McTeigue discloses taste masked pharmaceutical particles and tablets made from them. The core of the taste masked particles could comprise numerous active ingredients including ibuprofen. See [0013] The taste masked coating preferably forms about 5-50 weight percent of the coated taste masked particles. See [0025]. The coatings disclosed within McTeigue comprised a) an enteric polymer such as HPMCP b) an insoluble film forming polymer such as cellulose acetate and c) surfactants such as polysorbates (polysorbate-80 was specifically disclosed in the examples). See [0015]-[0021] and examples. A particularly preferred polymeric coating comprised about 53% wt HPMCP 43% CA and 4% polysorbate. While Mcteigue discloses that the chewable tablet can contain conventional ingredients such as cellulose and its derivatives as binders, the reference is silent in regards to the specific cellulose

derivatives contemplated, thus the reference does not teach the claimed hydroxyalkylcellulose. The amount of cellulosic polymer used in McTeigue was around 10% by weight of the total dosage form (see example 5, microcrystalline cellulose).

Percel is disclosed above and is used primarily for the disclosure within that HPMC and HPC within applicants claimed MW range was already well known at the time of applicants claimed invention to be useful as a binder in chewable tablets.

It would have been prime facie obvious at the time of the invention to a person of ordinary skill in the art to add or exchange the cellulose binders of McTeigue with the HPMC or HPC cellulose binders disclosed within Percel. One of ordinary skill in the art would have had a high expectation of success in making such a substitution since both references are drawn to chewable tablets and the cellulosic binders of each are used for the same purpose. It is generally considered to be prime facie obvious to combine or exchange compounds each of which is taught by the prior art to be useful for the same purpose in order to form a composition that is to be used for an identical purpose. The motivation for combining them flows from their having been used individually in the prior art, and from them being recognized in the prior art as useful for the same purpose. As shown by the recited teachings, instant claims are no more than the combination of conventional components such as cellulosic binders for use in chewable tablets. It therefore follows that the instant claims define prime facie obvious subject matter.

Claims 1-4,8-12 and 15-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Percel et al. (US 6,451,345 B1) in view of Urquhart et al. (US 4,851,232).

Percel is disclosed above; while Percel discloses the use of HPMC in making a tablet containing coated particles the reference does not disclose HPMC within applicants claimed MW for HPMC in dependant claim 2.

Urquhart also discloses tablets containing coated particles suspended in a cellulose material including HPMC. See abstract, figures and col 3 lin 66-col 4 lin 47. The reference discloses numerous types of HPMC within applicants claimed MW range and viscosity range. See col 5 lin 19-col 6 lin 15.

It would have been prime facie obvious at the time of the invention to a person of ordinary skill in the art to add or exchange the HPMC polymers of Percel with the HPMC polymers disclosed within Urquhart. One of ordinary skill in the art would have had a high expectation of success in making such a substitution since both references are drawn to oral dosage forms such as tablets and the cellulosic materials of each are used for the same general purpose, suspending active coated particles. It is generally considered to be prime facie obvious to combine or exchange compounds each of which is taught by the prior art to be useful for the same purpose in order to form a composition that is to be used for an identical purpose. The motivation for combining them flows from their having been used individually in the prior art, and from them being recognized in the prior art as useful for the same purpose. Furthermore one of ordinary skill in the art would also be motivated to experiment with varying molecular weights of HPMC in order to adjust the properties of the tablet, including the release rate and processability of that tablet. As shown by the recited teachings, instant claims are no more than the combination of conventional components of cellulosic materials for use in

suspending coated particles within a tablet formulation. It therefore follows that the instant claims define prime facie obvious subject matter.

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 9:30-6:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618